

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JP004-PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/017182	International filing date (<i>day/month/year</i>) 18.11.2004	Priority date (<i>day/month/year</i>) 21.11.2003
International Patent Classification (IPC) or national classification and IPC C12N15/09, C12Q1/68, G01N33/50, G01N33/15		
Applicant BIO-THINK TANK CO., LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>1-13</u>	YES
	Claims	<u></u>	NO
Inventive step (IS)	Claims	<u>2, 3</u>	YES
	Claims	<u>1, 4-13</u>	NO
Industrial applicability (IA)	Claims	<u>1-13</u>	YES
	Claims	<u></u>	NO
2. Citations and explanations (Rule 70.7)			
<p>Document 1: Nucleic Acids Research, Vol. 31, No. 2, 15 January 2003, pages 700 to 707</p> <p>Document 2: JP 2003-116543 A (Tosoh Corp.), 22 April 2003</p> <p>Document 3: Science, Vol. 294, 2001, pages 853 to 858</p> <p>Document 4: Nucleic Acids Research, Vol. 32, No. 3, 09 February 2004, pages 936 to 948</p> <p>The inventions set forth in claims 1 and 4 to 13 do not involve an inventive step in the light of the inventions disclosed in documents 1 to 3 cited in the international search report.</p> <p>Document 1 indicates that it is possible to evaluate the RNAi activity of a gene by:</p> <p>constructing an expression vector wherein a target expression molecule, which contains a target sequence and an expression regulation domain for regulating the expression of the RNA that includes said target sequence, has been bonded to the nucleic acid to be evaluated, which is evaluated in order to determine whether or not said nucleic acid exhibits an RNAi activity against the RNA that includes said target sequence;</p> <p>introducing said expression vector into a cell; and</p> <p>analyzing the phenotype of the cell.</p>			

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p>Meanwhile, document 2 discloses a method for evaluating the toxicity or the like of a substance based on the expression of target RNA within a cell; therein, the substance is supplied to the interior of an expression system capable of expressing the target RNA in order to evaluate whether or not the target cells are transcribed based on whether or not the target RNA is expressed.</p> <p>Methods for evaluating the RNAi activity of a nucleic acid are well known, as disclosed in document 1, and thus it is considered possible to conceive that RNA interference is one type of toxicity that may be exhibited by the substance to be tested in the evaluation method disclosed in document 2.</p> <p>Such being the case, it is considered to be easy for a person skilled in the art to conceive of attempting to evaluate the RNA interference characteristics of a substance to be tested by means of the invention disclosed in document 2; likewise, it is also considered to be easy for a person skilled in the art to conceive of employing the nucleic acid from the invention disclosed in document 1 as the substance to be tested in the invention disclosed in document 2.</p> <p>In addition, the fact that it is necessary to provide a control when carrying out an evaluation is considered to have been well known on the priority date of the present application. Therefore, it is not considered to be especially difficult to apply the abovementioned well-known feature and provide a control when attempting to evaluate the RNA interference characteristics of a substance by means of the invention disclosed in document 2; likewise, it is not considered</p>

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
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to be especially difficult to configure so that target RNA with a sequence that is not affected by RNA interference is used as a control when evaluating RNA interference by means of the invention disclosed in document 2.

Moreover, it is not considered to be especially difficult to conceive of evaluating miRNA activity, which was known to be one type of RNAi activity on the priority date of the present application (if necessary, refer to document 3), by means of a method for evaluating genes that express an RNAi activity as derived from the inventions disclosed in documents 1 and 2.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ in written format
- ☒ in computer readable form
- c. time of filing/furnishing
- ☒ contained in the international application as filed
- ☐ filed together with the international application in computer readable form
- ☐ furnished subsequently to this Authority for the purposes of search and/or examination
- ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."